

DETAILED ACTION

1. In response to an error made in the last Office action, the following corrective action is taken.

The period for reply of 3 MONTHS set in said Office Action is restarted to begin with the mailing date of this letter.

2. A corrected copy of the last Office Action is enclosed.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, are drawn to an apparatus.

Group II, claim(s) 8-12, are drawn to a method.

4. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical features in both group is the homogenization compartment with the rotor and stator. These elements cannot be a special technical feature under PCT Rule 13.2

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because these elements are shown in the prior art. US Patent 4416548 teaches the homogenization compartment with the rotor and stator as claimed in claims 1-12.

5. During a telephone conversation with Duane Byers on 9/24/08 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-12 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "11" has been used to designate both a stator and a rotor in Figure 7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: “wall (8) of the homogenization compartment (1)” (Page 5 Line 28-20) needs to be – homogenization compartment wall (8) -- to make specification clearer. Correction **throughout the specification** is necessary to make it clearer. Appropriate correction is required.
8. The disclosure is objected to because of the following informalities: “end (9) of the mixing system (4)” (Page 5 Line 29-30) needs to be – mixing system end (9) -- to make specification clearer. Correction **throughout the specification** is necessary to make it clearer. Appropriate correction is required.
9. The disclosure is objected to because of the following informalities: “tip (6) of said hollow tube” (Page 6 Line 14-15) needs to be – hollow tube tip (6) -- to make specification clearer. Correction **throughout the specification** is necessary to make it clearer. Appropriate correction is required.
10. The disclosure is objected to because of the following informalities: The following numbering element is inconsistent with respect to the terminologies: “inlet (2)” (Page 5 Line 17) is inconsistent with “inlet (3)” (Page 5 Line 18). Correction **throughout the specification** is necessary to make it clearer. Appropriate correction is required.
11. The disclosure is objected to because of the following informalities: The following numbering element is inconsistent with respect to the terminologies: “homogenization compartment (1)” (Page 5 Line 26) is inconsistent with “homogenization chamber (1)”

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(Page 15 Line 37). Correction **throughout the specification** is necessary to make it clearer. Appropriate correction is required.

12. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In claim 1(d) line 25, “final part (6)” lacks proper antecedent basis. Specification does not disclose numbering element (6) for final part. Appropriate correction is required.

13. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 3 on line 4, the claim refers to “claim 5” which is an improper dependency because claim 3 precedes claim 5. Appropriate correction is required.

Claim Objections

14. Claim 1 is objected to because of the following informalities: “homogenization compartment in the form of a cylinder (1)” (Line 11) needs to be – homogenization compartment (1) in the form of a cylinder -- to make the claim clearer. Appropriate correction is required.

Claim Rejections - 35 USC § 112

15. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "said system" in line 19. There is insufficient antecedent basis for this limitation in the claim. It is suggested to amend to – mixing system – or define a system earlier in the claim.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Carre et al. US Patent 4416548 (hereinafter Carre '548) (already of record). Examiner wishes to point out to applicant that claims 1-3 are directed towards an apparatus and as such will be examined under such conditions. The material worked upon or the processes of using the apparatus are viewed as recitation of intended use and are given no patentable weight (Please see MPEP 2114 R1-2115 R2 for further details).

18. **Regarding claim 1, Carre '548 discloses** a device for the continuous manufacture of microparticles or nanoparticles from at least one aqueous phase and

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one organic phase comprising a homogenization compartment in the form of a cylinder (cylindrical housing, Column 3 Line 40) which is defined by a tubular wall forming the casing of said cylinder and by a first side wall and a second side wall which are positioned at each end of said tubular wall (Figure 1 and Figure 2); the device additionally comprising a first inlet and a second inlet which pass through said first side wall (inlet 6...inlet 4, Figure 1, Column 3 Line 46-47) and which are appropriate for respectively delivering an organic phase and an aqueous phase to the homogenization compartment and an outlet (Figure 1 and Figure 2) appropriate for extracting a particle suspension from the homogenization compartment; the homogenization compartment including a mixing system comprising a rotor /stator (cylindrical rotor (2) and the stator ring (8), Figures 2, Column 3 Line 52) combination, characterized in that

- a) said side walls are positioned along a vertical plane (Figure 1),
- b) the axis of symmetry of said cylinder is positioned horizontally (Figure 2),
- c) the rotor is installed so that it rotates about a horizontal axis which passes through said second side wall (Figure 1),
- d) said first inlet is a hollow tube positioned in the extension of the axis of the rotor (Figures 1-2) and comprises a final part situated inside the rotor and inside the stator,
- e) the homogenization compartment exhibits a top side on which said outlet is situated (Figure 1).

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Note, Carre '548 discloses a tubular wall forming the casing of the cylindrical homogenization compartment as depicted in Figure 2. According to Figure 2, numbering element 1 is the cylindrical homogenization compartment which is defined by the tubular wall surrounding the outer surface of the compartment. In addition, Carre '548 discloses a first and second side walls which are depicted by Figure 1. The first side wall would be where the inlet (numbering element 6) and inlet (numbering element 4) joins and pass through the first side wall at the far right side of the homogenization compartment (numbering element 1). On the contrary, the second side wall is where the end of the rotor (numbering element 2) passes through the far left side wall and joins with an external rod that is connected to external bearing housing (numbering element 3). As shown in Figure 2, Carre '548 discloses the rotor (numbering element 2) and stator (numbering element 8). Also note, Carre '548 discloses a rotor in Figure 1 that depicts part of the rotor assembly passing through the second wall as stated in claim 1(c). Also note, Carre '548 discloses a hollow tube inlet that is positioned inside of the rotor and stator assembly as depicted by Figure 2. Examining Figure 1, the hollow tube inlet is shown projecting into the rotor. Therefore, it is the Examiner's position that the hollow tube inlet is positioned in the extension of the axis of the rotor as depicted by the combination of Figure 1 and Figure 2. Thus, a final part of the hollow tube inlet would be situated inside of the rotor and stator for optimizing the mixing and agitation of the aqueous and organic phases. Note, it is Examiner's position to give no weight to the material worked on or the process of using the apparatus as stated in claim 1.

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19. **Regarding claim 2, Carre '548 discloses** that the rotor and the stator are cylindrical in shape (cylindrical rotor 2...stator ring 8, Figures 2-4, Column 3 Line 52).

20. **Regarding claim 3, Carre '548 discloses** that the rotor and the stator comprise a row of teeth (pins 12...on both, Figure 3 and Figure 5, Column 4 Line 59-62) and that the spacing between the teeth is from 1 to 4 mm (Part number 12 Figure 5). Note, the exact spacing between the teeth is based on the desired size of the nanoparticles and microparticles.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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23. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carre et al. US Patent 4416548 (hereinafter Carre '548) (already of record) in view of Rasmussen, Carsten Ole WIPO Publication WO93/10665 (hereinafter Rasmussen '665) (already of record). Examiner wishes to point out to applicant that claims 4-6 are directed towards an apparatus and as such will be examined under such conditions. The material worked upon or the processes of using the apparatus are viewed as recitation of intended use and are given no patentable weight (Please see MPEP 2114 R1-2115 R2 for further details).

24. **From the aforementioned rejection, Carre '548 discloses** a cylindrical homogenization compartment that has an axis of symmetry positioned horizontally defined by a tubular wall comprising of a first and second wall which are positioned in a vertical plane, a first and second inlet, an outlet, a rotor and stator that are both cylindrical, a rotor that is installed about a horizontal axis which passes through the second wall, a first inlet hollow tube that positioned in the extension of the axis of the rotor, a final part inside the rotor and stator assembly, an outlet positioned on the top side of the homogenization compartment, and a rotor and stator assembly comprising a row of teeth with 1 to 4 mm spacing between them.

25. **However, Carre '548 failed to disclose** a first inlet comprising perforations of 1 to 20 and a diameter of 0.01 mm to 1 mm.

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26. **In another apparatus pertaining to the emulsification art, Rasmussen '665 discloses in regard to claim 4**, the first inlet comprises perforations (numbering element 11, Figure 1).

Therefore, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Carre '548 and Rasmussen '665 to obtain the invention as stated in claim 4; and to incorporate the perforations inlet taught by Rasmussen '665 with the homogenization compartment disclosed by Carre '558 for the benefit of optimizing a homogenous mixing of the organic and aqueous phases of the two inlets. In addition, the perforations allow an optimum uniform shape and size of the particles to be produced.

27. **Regarding claim 5, Rasmussen '665 discloses** that the number of perforations is from 1 to 20 (numbering element 11, Figure 1).

Therefore, it would have been obvious to a person of ordinary skill in the art to modify the teaching of Carre '548 and Rasmussen '665 to obtain the invention as stated in claim 5; and to incorporate the inlet with 1 to 20 perforations taught by Rasmussen '665 with the homogenization compartment disclosed by Carre '558 for the benefit of optimizing a homogenous mixing of the organic and aqueous phases of the two inlets. In addition, the perforations allow an optimum uniform shape and size of the particles to be produced.

28. **Regarding claim 6, Rasmussen '665 discloses** that the perforations have a diameter from 0.01 mm to 1 mm (numbering element 11, Figure 1). Note, Rasmussen

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'665 does not explicitly disclose the exact size of the perforations. However, the size of the perforations will be a function of the desired particle sizes. Thus, the diameter of the perforations is a result-effective variable that involves only routine skill in the art.

Therefore, it would have been obvious to a person of ordinary skill in the art to modify the teaching of Carre '548 and Rasmussen '665 to obtain the invention as stated in claim 6; and to incorporate the inlet with perforations having a diameter from 0.01 mm to 1 mm taught by Rasmussen '665 with the homogenization compartment disclosed by Carre '558 for the benefit of optimizing a homogeneous mixing of the organic and aqueous phases of the two inlets. In addition, the perforation diameter of 0.01 mm to 1 mm as disclosed by Rasmussen '665 would allow for optimizing an exact size and uniform shape desired for the nanoparticles or microparticles when used in conjunction with the homogenization compartment taught by Carre '548.

29. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carre et al. US Patent 4416548 (hereinafter Carre '548) (already of record). Examiner wishes to point out to applicant that claim 7 is directed towards an apparatus and as such will be examined under such conditions. The material worked upon or the processes of using the apparatus are viewed as recitation of intended use and are given no patentable weight (Please see MPEP 2114 R1-2115 R2 for further details).

30. **Regarding claim 7, Carre '548 does not explicitly disclose** the dimensions of the rotor/stator combination are such that said system occupies 4% to 40% of the volume of the homogenization compartment. However, the volume of the rotor/stator

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combination compared to the homogenization compartment will depend on process variables. The volume size of the rotor/stator combination relative to the homogenization compartment is a factor based on the desired production rate, amount of upstream feed supplied through the inlets, desired power consumption, and shearing force desire for organic phase and aqueous phases. Therefore, the volume size of the rotor/stator combination with respect to the homogenization compartment is a result-effective variable for optimizing the mixture of the organic and aqueous phases (Column 5 Line 20-24).

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dalziel et al. PGPUB Publication US2003/0152500A1.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ninh V. Le whose telephone number is (571)270-3828. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Ortiz can be reached on (571)272-1206. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NVL

***/Angela Ortiz/
Supervisory Patent Examiner, Art Unit 4151***